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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
LANDSMAN, ROBERT S	

ART UNIT	PAPER NUMBER
1647	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/586,499	ITOH ET AL.	
	Examiner	Art Unit	
	ROBERT LANDSMAN	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 August 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-19* is/are pending in the application.

4a) Of the above claim(s) *1-3, 6, 7, 13, 14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *5/28/08; 10/23/06*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. Formal Matters

Applicant's election of Group I, claims 1-3, 6, 7, 13 and 14 as drawn to EGFR479-488 in the reply filed on 8/15/08 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Therefore, this Restriction is deemed proper and is made FINAL.

2. Specification

A. Though none could be found, Applicant is advised that embedded hyperlinks and/or other forms of browser-executable code are impermissible and require deletion. The attempt to incorporate subject matter into the patent application by reference to a hyperlink and/or other forms of browser-executable code is considered to be an improper incorporation by reference. See MPEP 608.01(p), paragraph I regarding incorporation by reference.

B. Though none could be found, trademarks should be capitalized wherever they appears and be accompanied by the generic terminology. Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

C. Though none could be found, any U.S. or Foreign Applications cited in the specification which have since issued should be updated with the corresponding Patent No.

3. Claim Rejections - 35 USC § 112, first paragraph – scope of enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

A. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for EGFR800-809, 124-132, 54-62, 479-488 and 1138-1147, does not reasonably

provide enablement for any other EGFR-derived peptide capable of inducing CTL and a specific antibody response, nor for any "**derivatives**" or "**mutants**" thereof.. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

In In re Wands, 8USPQ2d, 1400 (CAFC 1988) page 1404, the factors to be considered in determining whether a disclosure would require undue experimentation include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims.

The breadth of the claims is excessive with regard to Applicants claiming all EGFR-derived peptides capable of inducing CTL and an antibody **other than the 5 recited in claim 2**. While Applicants do deserve some breadth and would be entitled to any peptide of the specific EGFR sequence disclosed in the instant specification which comprises the specific residues of claim 2 (though, as discussed below under 35 USC 112, second paragraph, it is not clear to which organism the specific amino acid residues correspond), Applicants have not provided any guidance or working examples of any EGFR "derivatives" or "mutants" which meet the claim limitations. It appears that Applicants have only identified specific peptides of an EGFR itself. Based on this lack of guidance and working examples, it would not be predictable to the artisan how to make a functional EGFR "derivative", "mutant", or any other peptide other that those recited in claim 2, which meets the limitations of the claims.

For these reasons, the Examiner concludes that undue experimentation would be required to practice the claimed invention.

4. Claim Rejections - 35 USC § 112, first paragraph – written description

A. Claims 1, 3, 6 and 7 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

These are genus claims. EGFR "**derivatives," "mutants" or other than those comprising the residues of claim 2** would have one or more amino acid substitutions, deletions, insertions and/or additions to said EGFR.

The scope of the claims includes numerous structural variants, and the genus is highly variant because a significant number of structural differences between genus members is permitted. Although these types of changes are routinely done in the art, the specification and claims do not provide any guidance as to what changes should be made. Structural features that could distinguish compounds in the genus from others in the peptide class are missing from the disclosure. No common structural attributes identify the members of the genus. The general knowledge and level of skill in the art do not supplement the omitted description because specific, not general, guidance is what is needed. Since the disclosure fails to describe the common attributes or characteristics that identify members of the genus, and because the genus is highly variant, EGFR, alone, is insufficient to describe the genus. One of skill in the art would reasonable conclude that the disclosure fails to provide a representative number of species to describe the genus. Thus, Applicant was not in possession of the claimed genus at the time the invention was made.

5. Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

A. Claims 2, 13 and 14 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is not clear as to what SEQ ID NO the recited residues correspond. Therefore, the metes and bound of the claims are unclear.

6. Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

A. Claims 1, 3, 6, 7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Okugawa et al. (Eur. J. Immunol. Reference AL on the 1449 submitted 10/23/08.

The claims recite an EGFR-***derived peptide or mutant thereof*** which is capable of inducing CTL and an antibody specific for said peptide (claim 1). Claim 3 recites that the peptide is 8-50 residues. Claims 6, 7, 13 and 14 recite pharmaceutical compositions comprising said peptide.

First, it is noted that the intended use of the composition in claims 7 and 14 do not alter the composition. Therefore, any reference which meets the limitations of claims 6 and 13 would meet the limitations of claims 7 and 14.

Second, the instant claims recite “derived from" and “mutant”. Therefore, since no limitations are placed on what a mutant or derivative can be, the claim encompasses any peptide which induces CTL and an antibody. There is no requirement that the derivative or mutant retain any characteristics of EGFR.

Okugawa teach an HER2-derived peptide consisting of 8 residues (TYPANASL) which can function an inducer of CTL and an antigen in vivo (Abstract). The use of this peptide in vivo demonstrates that it is a pharmaceutical composition. As discussed above, though a composition specific for cancer is not further limiting in absence of evidence to the contrary, Okugawa do teach the use of this composition in cancer patients (i.e. cancer vaccine), meeting the limitations of claims 7 and 14.

Though HER2 is a member of the EGFR family, as disclosed on page 2 of the specification, the fact that the claims recite "derived from" and “mutant” means that the peptide does not have to be related to EGFR. A mutant or derivative can have every amino acid of EGFR altered in absence of a specific definition of “derivative” and “mutant". However, even if the claims are limited to EGFR, the fact that the specification discloses that HER2/neu is a member of the EGFR family would mean that, in absence of evidence to the contrary, the HER2 peptide of Okugawa is an EGFR peptide as recited in the claims.

B. Claims 1, 3, 6, 7, 13 and 14 are rejected under 35 U.S.C. 102(b) as being anticipated by Noguchi et al. (The Prostate. Reference BD on the 1449 submitted 10/23/08.

The instant claims and issues are discussed above under Okugawa. The same issues and rationale apply here.

Noguchi teach numerous peptides, including those consisting of 8-50 residues (Abstract; Table II) which can function an inducer of CTL and an antigen in vivo (Abstract). The use of this peptide in vivo demonstrates that it is a pharmaceutical composition. As discussed above, though a composition specific for cancer is not further limiting in absence of evidence to the contrary, Noguchi do teach the use of this composition in cancer patients (i.e. cancer vaccine), meeting the limitations of claims 7 and 14.

Though PSA (prostate-specific antigen) is not a member of the EGFR family, the fact that the claims recite "derived from" and "mutant" means that the peptide does not have to be related to EGFR. A mutant or derivative can have every amino acid of EGFR altered in absence of a specific definition of "derivative" and "mutant". This rejection is a 102(b) since the publication date of Noguchi is more than one year prior to the PCT (2005).

7. Double Patenting

A. Though no rejection is being made at the present time, it is noted that numerous Obviousness-Type Double Patenting rejection could be made in view of the recitation in the instant claims of "derived' and "mutant". The following is a partial list of applications which could be considered for potential double patenting rejections -

Claim 1 of US 20080014186. Claims 38-39 of US 20070071767; US 20070066804; US 20070031433; US 20070031432 and claims 1-3 of U.S. Patents 7,432,352 and 7,427,660.

8. Conclusion

A. No claim is allowable.

Advisory information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Landsman, Ph.D. whose telephone number is (571) 272-0888. The examiner can normally be reached on M-F 10 AM – 6:30 PM (eastern).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Manjunath Rao can be reached on 571-272-0939. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Robert Landsman/
Primary Examiner, Art Unit 1647